UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,580	04/15/2004	Anja Kohlrausch	01-1491	8666

28501 7590 04/28/2009

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM USA CORPORATION
900 RIDGEBURY ROAD
P. O. BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER	
FINN, MEGHAN R	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
04/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,580	KOHLRAUSCH, ANJA	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,9 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed October 30, 2008 has been received and entered into present application. Claims 3, 6-8, 10-11 were canceled and claim 20 was added by applicant. Thus claims 1-2, 4-5, 9, 12-20 are pending.

Applicants' arguments, filed October 30, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant has submitted a translation of their German priority document, (DE 10319450.9) and thus the current effective filing date is now April 30, 2003. The Riedel et al. reference fails to qualify as prior art due to the 60/446,695 not providing support, that rejection is withdrawn. However Nakatani et al. still qualifies as a 102(e) with the filing date of 60/415,357, as this provisional document fully supports the teachings relied upon in Nakatani et al. Donsbach et al. and Lacourciere et al. also still qualify as prior art even under the new effective filing date.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 9, 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakatani et al. (US 2004/0110813 A1) in view of Donsbach et al. (US 2003/0130331 A1) in further view of Lacourciere et al. (Comparison of fixed-dose combination..) each already of record, for the reasons set forth at pages 3-6 of previous office action dated June 26, 2007, and those set forth at pages 5-8 of the office action dated April 30, 2008, of which reasons are herein incorporated by reference.

Applicant has amended the claims to specify hydrochlorothiazide as the diuretic claimed, however since the prior art already taught hydrochlorothiazide specifically this amendment does not overcome the rejection. Applicant has argued that it would not be obvious to combine, which is the same argument made before and addressed in the previous office action. There is clear motivation to combine. Applicant has claimed a composition. Both telmisartan and hydrochlorothiazide are known for treatment

hypertension and it's obvious to combine drugs known for the same purpose. Additionally, Nakatani et al. teaches both drugs together, they are just silent on the specific dosage of hydrochlorothiazide. It would be obvious to one of ordinary skill in the art at the time of the invention to look to another reference which teaches dosages of both drugs and Lacourciere et al. teaches both drugs and the dosage of telmisartan is the same as in Nakatani et al. . One of ordinary skill in the art would find this teaching by Lacourciere et al. to be a good starting place to optimize the dosage for such a composition. One of ordinary skill in the art at the time of the invention would be further motivated to use the crystalline sodium salt form of telmisartan that is taught in Donsbach et al. because of the advantages taught by that reference over non crystalline forms. It would have been obvious that the form of telmisartan in Donsbach et al. is preferable and it would have been obvious to use that from in the combination therapy of Nakatani et al.

Applicant has further argued that Nakatani et al. does not focus on the combination with diuretics and simply disclose that the telmisartan formulation could be used in the context of combination products and diuretics are one of many examples and hydrochlorothiazide is just one of many diuretics. The combination with diuretics may not be the primary focus of the patent application, however that is not required. The prior art is only required to teach or suggest the claimed invention. Nakatani et al. clearly teaches the combination of telmisartan with other products "for instance, together with a diuretic as the second active component" (page 4, [0078]) Here diuretic is the primary example of a combination product and actually the only other type of drug

talked about in combination, which is a much stronger teaching that applicant's statements which misleadingly argue that it was just one of many. Also, hydrochlorothiazide is the first example of a diuretic and is specifically mentioned as the second agent in the discussion about bilayers (page 6, [0128]), so it was clearly considered as an exemplary diuretic and given that the other prior art (Lacourciere et al.) teaches the combination with hydrochlorothiazide as the diuretic would also lead one of ordinary skill in the art to select that specific diuretic.

Applicant has also argued that none of the prior art teaches the crystalline sodium salt of telmisartan and hydrochlorothiazide. This statement is confusing because it is not clear if applicant means that none of them independently teach all of that, or if they together as a whole do not teach this. If applicant meant the first that would be an argument against a 102 anticipation rejection but not required of an obviousness rejection that each prior art teach all components. If applicant meant to argue the latter, the examiner disagrees for the reasons discussed above each of the elements are taught by the prior art and it would have been obvious to combine them. Applicant is perhaps also arguing that none of the prior art teaches the crystalline sodium salt of telmisartan, which is incorrect as Donsbach et al. clearly teaches that (page 1, [0011]).

Applicant has also argued that the prior art teaches away from a crystalline form of telmisartan and argues that both Nakatani and Donsbach et al. teach that crystallinity is not important however these comments are unsubstantiated and the examiner has been unable to find where in the prior art applicant believes these statements are made. Donsbach et al. clearly teaches a crystalline sodium salt form of telmisartan and

teaches that it is preferable so it would be hard to believe that one of ordinary skill in the art could read that disclosure and decide that a crystalline form is not desired.

For the newly added claim 20, applicant claims a composition comprising crystalline telmisartan sodium salt and one or more excipients including sorbitol. As discussed in the previous office actions and above Nakatani et al. teaches the combination of telmisartan and sorbitol and Donsbach et al. teaches the crystalline formulation. Thus for the reasons discussed above, claim 20 is also unpatentable over Nakatani et al. in view of Donsbach et al. in further view of Lacourciere et al.

Applicant's arguments were carefully considered but not deemed persuasive and thus the rejection of claims 1-2, 4-5, 9, 12-19 is **maintained.** The new rejection of claim 20 is necessitated by its addition to the claims.

Conclusion

Rejection of claims 1-2, 4-5, 9, 12-20 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614